K122521

510(k) Summary

JUN 1 1 2013

1. **Name/Address of Submitter:** **Itena Clinical**
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FRANCE

2. **Contact Person:** **Louis-Paul Marin**
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3. **Date Summary Prepared:** July 30th, 2012

4. **Devices Names:** Prevent Seal

5. **Device Classification:** II

6. **Common name:** Pit and Fissure Sealant

7. **Classification Product Code:** EBC; 21 CFR 872.3765

8. **Predicate Devices:**

HelioSeal F K932078
IPS Empress Direct Flow K103528

9. **Device Description:**

Prevent Seal is a fluoride releasing, white, light-cured acrylate resin. Not manufactured with Bisphenol A.

10. **Indication for Use:**

Prevent Seal is used by dental professionals primarily in young children:

- to fill and seal pit and fissure depressions (faults in the enamel) of teeth to prevent cavities;
- covering layer or "initial layer" in the fabrication of esthetically demanding composite restorations; and
- for repairs of composite restorations (in particular filling of voids, leveling out of porosities and minor chips).

11. Comparison with Predicate Products:

Prevent Seal is substantially equivalent in design, composition, intended use and performance to the predicate products listed above, notably as regards the following:

Technological Characteristics	Subject Device	HelioSeal F K932078	IPS Empress Direct Flow K103528
Type	light-cured acrylate resin	light-cured acrylate resin	light-cured acrylate resin
Intended Use	• to fill and seal pit and fissure depressions (faults in the enamel) of teeth to prevent cavities; • covering layer or "initial layer" in the fabrication of esthetically demanding composite restorations; • for repairs of composite restorations (in particular filling of voids, leveling out of porosities and minor chips).	To fill and seal the pits and fissures of teeth.	• As an intermediate or covering layer in the fabrication of esthetically demanding composite restorations • Repair of composite restorations (in particular filling of voids, levelling out of porosities and minor chips) • As a thin (< 0.5mm) initial layer under Class I and 11 restorations; • Small restorations of all types; • Extended fissure sealing; • Splinting of mobile teeth; • Blocking out of undercuts; • Repair of composite and ceramic veneers
Composition	UDMA TEGDMA HEMA Self-etching monomer Barium aluminoborosilicate glass initiators	UDMA TEGDMA Bis-GMA, titanium dioxide, initiators and stabilizers	UDMA Bis-GMA Tricyclodocandimethanoldimethacrylat Decamethylene dimethacrylate Barium glass, ytterbium trifluoride, dispersed silicon dioxide, mixed oxide and copolymer
Fluoride Release	Yes	Yes	No

12. Summary of Performance Testing:

The following laboratory results demonstrate that Prevent Seal performs as intended:

Flexural Strength (MPa)	250
Compressive Strength (MPa)	160
Shear Bond Strength to Etched Enamel (MPa)	35
Light Curing Time @ 23°C (sec)	20
Sensitivity to Ambient Light @ 22°C (sec)	75
Film Thickness (μm)	10
Radiopacity	Yes
Wavelength (nm)	465
Intensity of the light source (mW/sqcm)	600
Shade	White

13. Conclusion Drawn: Based on the above comparisons, the laboratory testing results, a search of the relevant literature and the organizational experience with Prevent Seal, Itena Clinical concludes that the subject device is substantially equivalent to the predicate devices (HelioSeal F K932078, and IPS Empress Direct Flow K103528) and that the subject device is safe and effective for its intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2013

Itena Clinical
C/O Mr. Louis-Paul Marin
Co-President
BCF Certification, Incorporated
500 Boul Cartier West
Laval H7V 5B7
CANADA

Re: K122521
Trade/Device Name: Prevent Seal
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: May 24, 2013
Received: May 28, 2013

Dear Mr. Marin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

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Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K122521

Device Name : **Prevent Seal**

Indications For Use :

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- For repairs of composite restorations (in particular filling of voids, leveling out of porosities and minor chips).

Prescription Use __X__ **AND/OR** **Over-The-Counter Use ____**
(Part 21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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